UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

United States et al.,	)	
***ex rel.* Mark Radcliffe**	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	**No. 1:05CV00089**
	)	
Purdue Pharma L.P., et al.,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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SUMMARY OF ARGUMENT

In his Third Amended Complaint,[1/] Relator Mark Radcliffe (hereinafter "Radcliffe"), a/k/a "John Femaledeer," asserts claims against Defendants Purdue Pharma L.P. and Purdue Pharma, Inc. (hereinafter collectively "Purdue") under the federal False Claims Act ("FCA"), 31 U.S.C. § 3729 et seq., and thirteen similar state statutes. For several independent reasons, the Complaint must be dismissed.

Radcliffe's Complaint is based on publicly disclosed information and not, as the FCA requires, on information he developed or discovered on his own. Moreover, the alleged false statements at the core of Radcliffe's allegations are nothing more than one side of an open, publicly-reported scientific debate. Radcliffe also released Purdue from all claims before he filed this suit, his Complaint fails to satisfy the federal fraud pleading requirements and various state filing requirements, and is, in significant respects, time barred. It is therefore no surprise that the federal government and all thirteen state governments named in the Complaint declined to intervene in this suit.

Pursuant to Rules 12(b)(1), 12(b)(6), and 9(b) of the Federal Rules of Civil Procedure, therefore, Purdue respectfully moves the Court to dismiss Radcliffe's Complaint with prejudice and grant Purdue such other relief as the Court deems just and equitable.

[1/] All references to "the Complaint" are to the Third Amended Complaint unless otherwise specified.

BACKGROUND AND STATEMENT OF FACTS

A. THE RADCLIFFE A/K/A "JOHN FEMALEDEER" EXTORTION ATTEMPT

Relator Mark Radcliffe is a former sales representative and District Manager who worked at Purdue from January 1996 to August 25, 2005. *See* Compl. ¶¶ 2, 14, 26; DX A5 at 2A (Severance Package and Release of Claims).[2/] During this time, he promoted OxyContin, Purdue's pain medication at issue here. Compl. ¶ 26.

In January 2005, Radcliffe, identifying himself only by the alias "John Femaledeer," contacted Purdue,[3/] accusing it of various wrongs including those he complains of here, and offering to "settle" what he claimed would be a massive FCA *qui tam* case in exchange for an investment by Purdue in a company he was starting. *See* DX A1- A4 (e-mails and documents sent to Purdue by "John Femaledeer" a/k/a Radcliffe).

During his first communication, on January 19, 2005, Radcliffe/Femaledeer explained that he had previously sought private counsel from two different law firms. DX A1 at 1. He further said he had discussed the prospects for a "*Qui Tam* claim" regarding "deceptive pharmacology" with two prosecutors from the U.S. Attorney's Office for the Western District of Virginia ("WDVA"), who were then three years into an investigation of Purdue's marketing of OxyContin. *See id.*; DX A2 at 1. Notwithstanding his claim that Purdue had engaged in this deceptive practice since 1996, Radcliffe/Femaledeer had remained at Purdue promoting OxyContin for an additional nine years.

[2/] Exhibits attached to this motion to dismiss are noted by "DX"; exhibits to the relator's Complaint are noted by "RX." In addition, a declaration authenticating Exhibits A1 – A8 is attached as Exhibit A. Due to the length of the exhibits, the exhibits were filed in paper on October 2, 2007, and are available in the clerk's office. Finally, the portions of the articles cited to have been highlighted in yellow for ease of reference.

[3/] Radcliffe/Femaledeer first contacted both a Purdue board director as well as its executive vice president and chief legal officer in an e-mail on January 19, 2005. DX A1.

Radcliffe/Femaledeer valued his FCA claim at approximately $45.6 million. DX A3 at 4. In exchange for his silence, he demanded $40 million in seed money from Purdue for his new company that he said would "import Anti-Terrorism technology from Israel to guard and protect the Physician-Patient Relationship against the onslaught of terrorism from doctor shoppers and drug abusers." *Id.*; A4 at 1-A (requesting a $20 million investment and $20 million in loans). Purdue declined Radcliffe/Femaledeer's settlement demand and advised that if he thought he had a viable claim, he ought to pursue it.[4/]

B. RADCLIFFE LEAVES PURDUE WITH AN ENHANCED SEVERANCE PACKAGE

Later that same year, 2005, Purdue restructured its sales force. Some employees were terminated; some, including Radcliffe, were offered the option of transferring positions. DX A5, at 2-A, 15. Radcliffe declined the offer. Instead, on August 1, 2005, he signed an agreement to leave Purdue with an enhanced severance package that included extended severance pay and insurance coverage through January 20, 2006. DX A5 at 1-8. He left Purdue on August 25, 2005. *Id*. at 2A.

As part of this agreement, Radcliffe signed and executed a Release, in which he "knowingly and voluntarily releas[ed] and forever discharge[d] [Purdue] . . . of and from any and all liability to [Radcliffe] for actions or causes of action, suits, [or] claims . . . whatsoever, in law or equity, which [Radcliffe] ever had, may now have or hereafter can, shall or may have."

[4/] It is undeniable that Radcliffe and Femaledeer are one and the same for a number of reasons. First, the allegations in Femaledeer's January 2005 fax are ***identical*** to those in Radcliffe's Complaint. *Compare* DX A3, *with* Compl. ¶¶ 32-41, 46-48. Second, Femaledeer attached or cited in his letter ***each and every one*** of the documents attached to or cited in Radcliffe's Complaint. *Compare* RX 1-6, *with* DX A3. Indeed, Exhibit 6 to the Complaint still reflects the fact that it was marked as Attachments 8 and 9 to Femaledeer's letter. *Compare* RX 6, *with* DX A3. Third, Radcliffe ultimately started the company for which Femaledeer sought funds, Algesiography, Inc. *See* DX A4, at 1 (Algesiography Prospectus sent to Purdue by Femaledeer). Radcliffe also registered an Internet domain name for Algesiography on October 25, 2003 (*see* DX B1 (Internet domain registration of algesiography.com); and his wife, Angie Radcliffe, filed a Form D with the SEC on September 29, 2003, for Algesiography, Inc. *See* DX B2 (Radcliffe's Form D Filing for Algesiography, Inc.).

Id. at 1-2 (Release ¶ 4(a)). Purdue gave Radcliffe more than forty-five days to consider the Release before signing it, urged him to review the Release with an attorney, and gave him seven days after he signed the agreement (August 1, 2005) to revoke the agreement. *Id*. at 3A, 6 (Release ¶13).

C. RADCLIFFE'S COMPLAINT

Two months later, on September 27, 2005, Radcliffe filed his original Complaint in this Court under seal. *See* Compl. [Dkt. 3]; Order Sealing Case [Dkt. 1].[5/]

Radcliffe's allegations concern Purdue's pain medication OxyContin and its relative potency as compared to morphine-based medications, such as MS Contin.[6/] He alleges the "[d]efendant[s] asserted falsely and fraudulently to [doctors], through its salesmen's oral misrepresentations and in written form (the conversion ratio in the package insert), that it took only one milligram of OxyContin to give the same pain relief as two milligrams of MS Contin." Compl. ¶ 11.

OxyContin is a controlled-release, oxycodone-based pain medication approved by the U.S. Food and Drug Administration ("FDA") in December 1995 "for the management of moderate to severe pain" in patients who need an opioid pain medication "for more than a few days."[7/] RX 2 (Dec. 1995 OxyContin package insert, "Indications and Usage").[8/] The FDA-

[5/] Since then, Radcliffe amended his Complaint three times, on November 6, 2006 [Dkt 10], on January 17, 2007 [Dkt. 15; 19], and on June 5, 2007 [Dkt. 27; 28]. The Complaint was unsealed on June 4, 2007 (Order [Dkt. 26]), after the United States and the thirteen states named in this Complaint declined to intervene in this action (*see* Gov't Notice of Election to Decline Intervention [Dkt. 22] (filed May 7, 2007)).

[6/] The heart of Radcliffe's allegations is that Purdue, through its sales representatives and its FDA-approved package insert, made two false representations to physicians. First, Purdue allegedly falsely claimed that OxyContin (controlled-release oxycodone) is twice as potent as MS Contin (controlled-release morphine). Compl. ¶ 11. Second, Purdue allegedly falsely told physicians that, because of this, OxyContin is less expensive than MS Contin. *Id*. Because the claim about the cost of OxyContin is based on the relative potency claim (*see id.* ¶ 34), there really is just one alleged false representation at issue: that OxyContin is twice as potent as controlled-release morphine (such as MS Contin).

[7/] In July 2001, the approved FDA packaging was altered slightly to read: "the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time." DX C at 3

(Footnote continued on next page)

approved package insert for OxyContin contains a conversion table, which recommends that doctors convert patients from morphine to OxyContin using a 2:1 conversion ratio, meaning that doctors should prescribe half as much OxyContin, by weight, as the prior morphine prescription. RX 2 at 2, tbl.3; DX C at 7, tbl. 4; DX D at 22, tbl.4. Purdue's FDA-approved package insert also makes clear: (1) it is only a recommendation; (2) "[t]he recommended doses . . . are only a starting point, and close observation and frequent titration [i.e. "adjustments"] are indicated until patients are stable on the new therapy;" (3) other factors must be considered in determining the appropriate dose; and (4) "[n]o fixed conversion ratio is likely to be satisfactory in all patients." RX 2 at 2; DX C at 6-7; DX D at 21-23.

Radcliffe contests Purdue's alleged marketing statements that OxyContin is twice as potent as controlled-release morphine in repeated doses. Compl. ¶ 11. According to Radcliffe, Purdue's claims are incorrect because, while OxyContin is approved for repeated doses, Purdue's findings are allegedly based on a "single-dose study" – that is, a study in which patients were evaluated after being given a single dose rather than repeated doses of the test drug. *Id.* ¶ 12. Radcliffe alleges that the "professional literature" establishes that in fact OxyContin[9/] is equally as potent as morphine. *Id*. Radcliffe offers one example of such "literature": a table printed in a 1992 U.S. Department of Health and Human Services "Clinical Practice Guideline" on acute pain management.[10/] *Id*. Radcliffe's Complaint indicates his allegations are also based on a

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(July 2001 OxyContin package insert, "Indications and Usage"). This remains the labeling instruction today. *See* DX D, at 9 (current package insert).

[8/] Radcliffe attached an incomplete July 2001 package insert as RX 3. For the Court's convenience, a complete copy in larger print is attached hereto as DX C.

[9/] Some of this "literature" involves studies of oxycodone generally – both immediate-release oxycodone and controlled-release oxycodone. References herein to studies or articles about OxyContin include studies or articles about controlled-release oxycodone generally.

[10/] Agency for Health Care Policy & Res., U.S. DHHS, *Clinical Practice Guideline No. 1, Acute Pain Management: Operative or Medical Procedures and Trauma*, App. C2, at 112-13 (1992) (RX 5; DX F1). The

(Footnote continued on next page)

handful of other publicly available scientific publications and the statements of physicians who pointed him to some of these publications. *Id.* ¶¶ 16, 17, 24. Radcliffe further alleges Purdue knew OxyContin was equal in potency to morphine – not twice as potent – because Purdue suggested in a 1991 MS Contin (controlled-release morphine) training manual that patients be converted from oral oxycodone products to MS Contin at a dosage ratio of 1:1. *Id.* ¶ 12; RX 4.[11/]

D. THE RELATIVE POTENCY OF OXYCONTIN AND MORPHINE IS PART OF A LONG-STANDING, PUBLIC SCIENTIFIC DISPUTE

Radcliffe's allegations relate to an ongoing scientific debate on the relative potency of oxycodone and morphine.

1. The Shifting Debate Regarding the Relative Potency of OxyContin and Morphine

Originally, in the 1970s and 1980s, professionals reported in medical journals and like publications that oxycodone was twice as potent as morphine taken orally, and that morphine taken via other methods such as injection, *i.e.*, "parenterally," was six times as potent as morphine taken orally.[12/] In the 1980s and early 1990s, some practitioners began observing that morphine taken intravenously was only two or three times as potent as oral morphine. Extrapolating from these observations about different forms of morphine, some medical

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federal government published this "clinical practice guideline to help surgeons, nurses, and anesthesiologists manage acute postoperative pain more effectively." *See* http://www.ahrq.gov/clinic/medtep/acute.htm#acutesum (last visited Oct. 1, 2007). The current version of this document on the Department of Health and Human Services' website states, "THIS DOCUMENT IS NO LONGER VIEWED AS GUIDANCE FOR CURRENT MEDICAL PRACTICE." *See* http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat6.chapter.8991 (last visited Oct. 1, 2007).

[11/] This last claim is a spectacular non-sequitor, as explained *infra* at note 25.

[12/] *See, e.g.*, Kathleen M. Foley, *The Treatment of Cancer Pain*, 313 (2) New Eng. J. Med. 84, 90 tbl.6 (1985), DX E1; Charles E. Inturrisi & Kathleen M. Foley, *Narcotic Analgesics in the Management of Pain*, *in* Analgesics: Neurochemical, Behavioral, and Clinical Perspectives 259-62 tbl.1 (Michael J. Kuhar & Gavril W. Pasternak eds., 1984), DX E2; Raymond W. Houde, *Systemic Analgesics and Related Drugs: Narcotic Analgesics*, *in* 2 Advances in Pain Research and Therapy 263, 266 tbl.1 (John J. Bonica & Vittorio Ventafridda eds. 1979), DX E3; Raymond W. Houde, *The Use and Misuse of Narcotics in the Treatment of Chronic Pain*, *in* 4 Advances in Neurology 527, 536 tbl.2 (John J. Bonica ed., 1974), DX E4.

publications began reporting that oral oxycodone (such as in OxyContin) and oral morphine are equally potent, at least when morphine is dosed repeatedly.[13/]

These new reports by no means reflected a scientific consensus. During this same time-period and after, other scientists and professionals, including those at Purdue, continued to find oral oxycodone to be twice as potent as oral morphine.[14/]

2. Current State of the Science

Contemporary authorities increasingly recognize today that oxycodone is approximately twice as potent as morphine. For example, while the Complaint references the Third Edition of the *Textbook of Pain*, the Fourth Edition[15/] recognizes that "by mouth oxycodone is about 1.5-2 times more potent than morphine."[16/] Other scholarly medical sources recognize that oxycodone is either one and one-half or two times as potent as morphine, or that the relative potency falls

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[13/] For instance, Radcliffe cites in his Complaint the following sources for his allegation that OxyContin is equally as potent as morphine: Agency for Health Care Policy & Res., U.S. DHHS, *Clinical Practice Guideline No. 1, Acute Pain Management: Operative or Medical Procedures and Trauma* at 6-7 (1992) (Compl. ¶ 12, RX 5; DX F1); Robert G. Twycross, *Opioids, in* Textbook of Pain 943, 953 tbl. 49.7 (Patrick D. Wall & Ronald Melzach eds., 3d ed. 1994) (cited at Compl. ¶ 17; DX F2). Radcliffe also references "the United States Pharmacopeia." Compl. ¶ 2. The United States Pharmacopeia is not a publication but a body that produces multiple publications, including the *United States Pharmacopeia - Dispensing Information* ("*USP DI*"), an annually updated reference publication. Volume I of the 1996 edition of the *USP DI* contains a table that shows OxyContin and oral morphine as equally potent. *See* DX F3, at 2238 tbl.2. Radcliffe's First Amended Complaint also cited a second HHS "Clinical Practice Guideline," which Purdue has identified as *Clinical Practice Guideline No. 9, Management of Cancer Pain* (1994). *See* DX F4, at 52 tbl.10, 54 tbl.11.

[14/] *See infra* note 17.

[15/] The *Textbook of Pain* was one of "the very first references to address pain management." *See* http://www.textbookofpain.com. In this periodically updated scholarly medical reference, articles from a variety of scientists and medical practitioners are included, which address many topics, including information on the various pain medications available. *Id*. It was first published in 1984, and has been updated since; the last version was the Fifth Edition, which was published in 2006. *Id*.

[16/] Robert G. Twycross, *Opioids, in* Textbook of Pain 1187, 1202 tbl. 51.11 (Patrick D. Wall & Ronald Melzack eds., 4th ed., 1999), DX G12. The fifth edition also includes an article that states that oxycodone is one and one-half times as potent as morphine. Stephan A. Schug & Neelima Gandham, *Opioids: Clinical Use, in* Wall and Melzack's Textbook of Pain 448, 453 tbl. 28.2 (Stephen B. McMahon & Martin Koltzenburg eds., 5th ed. 2006),
DX G13.

within that range.[17/] At the very least, this issue – how potent oxycodone is compared to morphine – has been the subject of a legitimate scientific debate.

[17/] *See, e.g.*, Julia Riley et al., *No Pain Relief from Morphine? Individual Variation in Sensitivity to Morphine and the Need to Switch to an Alternative Opioid in Cancer Patients*, 14(1) Supportive Care in Cancer 56, 61 (2006), DX G1 (reporting the "easy conversion ratios (oral morphine/oxycodone, 2:1"); Christopher J. Watling, *Cancer Pain*, *in* 1 Neurological Therapeutics: Principles and Practice 286, tbl.25.5 (2d ed., John H. Nosworthy ed. 2006), DX G2 (reporting a 2:1 ratio); F. Coluzzi & C. Mattia, *Oxycodone: Pharmacological Profile and Clinical Data in Chronic Pain Management*, 71 Minerva Anestesiologica 451, 457 (2005), DX G3 ("[W]hen orally administered, as [a] result of its higher bioavailability, oxycodone has twice the potency of oral morphine on a milligram basis, with equivalent analgesic efficacy. The recommended conversion ratio for oral oxycodone to oral morphine is 1:2 mg."); Eija Kalso, *Oxycodone*, 29 (Supp. 2005) J. Pain & Symptom Mgmt. S47, S51-52 (2005), DX G4 (reporting the relative potencies of oxycodone/morphine "vary from 3:4 to 1:2"); Ralph A. Lugo & Steven E. Kern, *The Pharmacokinetics of Oxycodone*, 18(4) J. Pain & Palliative Pharmacotherapy 17, 18, 26 (2004), DX G5 ("The relative potency of oral oxycodone is between 1.5 and two times that of oral morphine." "While this [2:1] ratio may be somewhat conservative, this may be appropriate due to incomplete cross-tolerance among opioid analgesics."); Karen J. Souter & Dermot Fitzgibbon, *Equianalgesic Dose Guidelines for Long-Term Opioid Use: Theoretical and Practical Considerations*, 23(4) Seminars in Anesthesia Perioperative Med. & Pain 271, 274 tbl.3, 277 (2004), DX G6 (recommending a ratio of 2:1 for morphine-to-oxycodone conversions, and a ratio of 1.5:1 for oxycodone-to-morphine conversions); Mellar P. Davis et al., *Normal-Release and Controlled-Release Oxycodone: Pharmacokinetics, Pharmacodynamics, and Controversy*, 11(2) Supportive Care in Cancer 84, 86-87, 90 (2003), GX 7 (reporting that a majority of the studies show a 2:1 or 1.5:1 ratio when converting from MS Contin to OxyContin); Jose Pereira et al., *Equianalgesic Dose Ratios for Opioids: A Critical Review and Proposals for Long-Term Dosing*, 22(2) J. Pain & Symptom Mgmt. 672, 678-79 tbl.4 (2001), DX G8 (reviewing studies conducted in the repeat dosing context, and observing that oxycodone dosed intravenously is 1.5 to 2 times relatively more potent than morphine dosed orally); Jeannine M. Brant, *Opioid Equianalgesic Conversion: The Right Dose*, 5(4) Clin. J. Oncology Nursing 163, 163 (2001), DX G9 (reporting that oxycodone is 1.5 or 2 times more potent than morphine); Robert Anderson et al., *Accuracy in Equianalgesic Dosing: Conversion Dilemmas*, 21(5) J. Pain & Symptom Mgmt. 397, 399 (2001), DX G10 ("Thus, when converting from MS to Oxy, a 2:1 ratio . . . could be used."); GW Hanks et al., *Morphine and Alternative Opioids in Cancer Pain: the EAPC Recommendations*, 84 Br. J. Cancer 587, 591 (2001), DX G11 ("[T]he equianalgesic dose of oral oxycodone is between half and two thirds that of oral morphine."); Twycross, *supra* note 16, at 1202 tbl. 51.11, DX G12 (1.5:1 to 2:1); GR Lauretti et al., *Comparison of Sustained-Release Morphine with Sustained-Release Oxycodone in Advanced Cancer Patients*, 89(11) Br. J. Cancer 2027 (2003), DX G14 (reporting a study in which a 1:1.8 ratio was used); Robert F. Kaiko et al., *Analgesic Onset and Potency of Oral Controlled-Release (CR) Oxycodone and CR Morphine*, 59 (2) Clin. Pharmacol. & Therapeutics 130 [Abstract PI-4] (1996), DX H1 ("Oral CR oxycodone and oral CR morphine are equianlgesic at a 1:2 dose ratio"); G.B. Curtis et al., *Relative Potency of Controlled-Release Oxycodone and Controlled-Release Morphine in Postoperative Pain Model*, 55 Eur. J. Clin. Pharmacol. 425, 428 (1999), DX H2 ("[O]ral oxycodone was 1.8 times more potent than oral CR morphine for total effect and 2.2 times more potent for peak effect"); Robert F. Kaiko & Iwona Beczkowska, *Comparative Review of Daily Dose Requirements of OxyContin® and MS Contin® in Patients with Non-Malignant and Malignant Pain* [poster], IASP 9th World Congress on Pain, Aug. 22-27, 1999, Vienna, Austria, DX H3 ("Consistent with the results of single-dose relative potency studies, OxyContin was twice as potent as MS Contin."); Robert Salzman et al., *Can a Controlled-Release Oral Dose Form of Oxycodone be Used as Readily as an Immediate-Release Form for the Purpose of Titrating to Stable Pain Control*, 18(4) J. Pain & Symptom Mgmt. 271-9, 273 tbl. 1 (1999) (reporting a 2:1 ratio), DX H4; Eduardo Bruera et al., *Randomized, Double-Blind, Cross-Over Trial Comparing Safety and Efficacy of Oral Controlled-Release Oxycodone with Controlled-Release Morphine in Patients with Cancer Pain*, 16(10) J. Clin. Oncol. 3222, 3227 (1998), DX H5 ("Conversions from morphine to oxycodone using a 2:1 dose ratio essentially cover the range of observed dose ratios in this study and provide some assurance that patients . . . will not be overdosed on transfer to oxycodone."); B. Ginsberg, et al., *Conversion from IV PCA Morphine to Oral Controlled Release Oxycodone (OxyContin(R)) for Post-Operative Pain Management*, 86 Anesthesia & Analgesia [Abstr S271] (1998), DX H6 (reporting a 1.5:1 ratio when administered to patients 12-24 hours after surgery); David P. Benziger et al., *A Pharmacokinetic/ Pharmacodynamic Study of Controlled-Release Oxycodone*, 13(2) J. Pain & Symptom Mgmt. 75 (1997), DX H7 ("[T]he relative potency of oral oxycodone is approximately twice that or oral morphine."); Tarja Heiskanen & Eija Kalso, *Controlled-Release Oxycodone and Morphine in Cancer Related Pain*, 73(1) Pain 37 (1997) ("[T]he oral dose ratio of oxycodone to morphine has been recommended to be 1:2 to 2:3."), DX H8.

E. PURDUE HAS BEEN AN OPEN PARTICIPANT IN THIS SCIENTIFIC DISCUSSION

Purdue has repeatedly and openly reported both its own findings and those of competing scientists who found contrary results. For example, when Purdue submitted its New Drug Application ("NDA") for OxyContin to the FDA in December 1994, it explicitly reported the uncertainties surrounding OxyContin's relative potency and also reported that it found OxyContin to be twice as potent as morphine. *See* DX A6 at 11, 25 (excerpts from Purdue's Dec. 28, 1994, NDA OxyContin submission).

In addition, prior to OxyContin's approval, in 1995, Purdue conducted a controlled, single-dose study specifically designed to assess the relative potency of oral controlled-release oxycodone (such as OxyContin) and oral controlled-release morphine (such as MS Contin) – a study that Radcliffe cites repeatedly in his Complaint. This study was published in two peer-reviewed publications: an abstract of the study was published in the February 1996 issue of *Clinical Pharmacology & Therapeutics*[18/] and a full study report was published in the peer-reviewed *European Journal of Clinical Pharmacology* in 1999.[19/] The core finding of the study was that OxyContin is twice as potent as morphine.[20/] And, in the 1999 publication of the study, the Purdue authors discussed in detail that there was a scientific debate about oxycodone's potency, and reported the various findings of other researchers, including those with findings that oxycodone and morphine are equally potent.[21/]

[18/] Kaiko, *supra* note 17 (DX H1). The abstract reported that "[o]ral CR oxycodone and oral CR morphine are equianalgesic at a 1:2 dose ratio with both providing rapid onset for q12h [dosed every 12 hours] analgesics." *Id.*

[19/] Curtis, *supra* note 17 (DX H2).

[20/] *Id*. at 428.

[21/] *Id*. Purdue also presented the results of this study as a poster at the American Pain Society's Fifteenth Annual Meeting in November 1996. *See* DX H1 (including APS abstract no. 674).

Purdue later conducted a larger review of data from several clinical studies, designed to mimic clinical settings. The review found that "[c]onsistent with the results of single-dose relative potency studies, OxyContin [is] twice as potent as MS Contin [controlled-release morphine] in relieving both non-malignant and malignant pain."[22/] It is this review that led Purdue to train its sales representatives that the finding that OxyContin is twice as potent as morphine is supported by "the ratio of dosages derived from numerous, separate, repeat-dose studies of oral morphine and oral oxycodone in which the dosages of each preparation were titrated to stable pain control without unacceptable side effects." RX 6 (OxyContin "Answer Guide").

Furthermore, Purdue repeatedly engaged in the ongoing scientific debate, defending publicly its findings that OxyContin is twice as potent as morphine. For example, in 1999 and again in 2000, research teams affiliated with Roxane Pharmaceuticals, a company that produces a generic version of MS Contin (controlled-release morphine), published articles that suggested that morphine and OxyContin are equally potent.[23/] In both cases, officials from Purdue or from an independent associated company responded with a Letter to the Editor reporting Purdue's finding that OxyContin is twice as potent as morphine, triggering a counter-response from the authors.[24/]

[22/] Kaiko & Beczkowska, *supra* note 17 (DX H3). Purdue presented the results of this study in a poster at the International Association for the Study of Pain's Ninth World Congress of Pain, in August 1999. *Id.*

[23/] Marco Pappagallo et al., *Palliative Care and Hospice Opioid Dosing Guidelines with Breakthrough Pain (BP) Doses*, 17(6) Am. J. Hospice & Palliative Care 407, 408 tbl.1 (2000), DX I1 (reporting that 90 mg of controlled-release morphine is equally potent as 80 mg of OxyContin); Donna S. Zhukovsky et al., *The Relative Potency Between High Dose Oral Oxycodone and Intravenous Morphine: A Case Illustration*, 18(1) J. Pain & Symptom Mgmt. 53, at 53 (1999) (reporting a 1:1 ratio), DX I2.

[24/] Letter to the Editor, Re: *Conversion Ratio and Cost of Oxycodone*, and Authors' Reply, 18(3) Am. J. Hospice & Palliative Care, 159, 159-60 (2001), DX J1; Letter to the Editor, Re: *The Relative Potency Between High-Dose Oral Oxycodone and Intravenous Morphine*, and Author's Response, 19(5) J. Pain & Symptom Mgmt. 326-27 (2000), DX J2.

Similarly, Purdue has openly and consistently explained its position to physicians and others who inquired. *See* DX A7 at 1-4 (Purdue's current standard response letter regarding questions about converting to OxyContin from morphine). It thus tells doctors, after explaining in painstaking detail the history of findings regarding the relative potency of OxyContin and morphine, *see supra* at 6-11: "[i]t is important to note that when a difference of opinion exists in analgesic potency, it is usually advisable to err on the conservative side so as to maximize the safety of the patient."[25/] DX A7 at 3.

F. THE GOVERNMENT'S INVESTIGATION

Radcliffe's allegations have been investigated by the government. After Radcliffe contacted two Assistant United States Attorneys in the Western District of Virginia, they issued a Grand Jury Subpoena to Purdue on August 2, 2005, demanding all documents related to the relative potency of OxyContin versus MS Contin. DX K (Request 4 of Grand Jury Subpoena 513). That same month the government began questioning Purdue employees before a grand

[25/] Purdue has also stressed that while it is safer to assume oxycodone is twice as potent as morphine when converting patients from oral morphine to oral oxycodone, the prudent approach is to assume that oxycodone and morphine are equally potent when converting patients *in the other direction*. *See* DX A7 (Purdue's medical response letter, *OxyContin®/Oral Morphine Conversion Information*); Robert F. Kaiko, et al., *The Use of Controlled Release Opioids*, *in* Cancer Pain Management: Principles and Practice 71 tbl. 8-1, 80 tbl. 8-6 (Winston C.V. Parris ed. 1997) (showing the conversion table from the OxyContin package insert, but also recommending 1:1 ratio for conversions to controlled-release morphine), GX H9; *see also* DX C at 7 (specifying that the conversion table in the OxyContin package insert is only for conversions ***to*** OxyContin), DX D at 22 (same); Curtis, *supra* note 17, at 428 (DX H2). *Cf*. Anderson, *supra* note 17, at 399 (DX G10) ("In these studies, oral MS:Oxy [morphine:oxycodone] dose ratios range from 1:1 to 2.3:1, a range which may reflect bioavailability differences and incomplete cross-tolerance. . . . Given these data, then, it would seem prudent to use the more conservative dose ratio in determining a conversion to an around-the-clock dose . . . . Thus, when converting from MS to Oxy, a 2:1 ratio (MS:Oxy) could be used versus using a 1:1 ratio when converting from Oxy to MS."). Thus, Purdue recommended in its 1991 MS Contin training manual to use a 1:1 ratio when converting *to morphine* (Compl. ¶ 12) and in the OxyContin package insert to use a 2:1 ratio when converting *from morphine* (Compl. ¶ 11). There is, however, no contradiction here, only safe and conservative medical guidance. If Purdue instead had recommended a 1:1 conversion ratio in its OxyContin package insert as Radcliffe suggests, then a patient taking 120 mg/day of oral morphine would be started on 120 mg/day of OxyContin – double the dose that Purdue recommends as a starting point. Beginning the patient on such a high dose could result in unnecessary side effects or even an overdose. Instead, Purdue recommends that when converting a patient from oral morphine to OxyContin, a physician would begin by prescribing half the amount of OxyContin (or in this example, 60 mg/day) and determine whether that amount relieves the patient's pain before deciding whether a higher dose is necessary. For the same reason, Purdue continues to recommend a 1:1 ratio for conversions from oral oxycodone to oral morphine, an approach that likewise starts the patient on a lower dose, and only suggests increasing the dose as the patient's reaction to the medication becomes clear. *E.g.*, RX 4 (excerpt from MS Contin training materials).

jury about Purdue's findings that OxyContin was twice as potent as morphine and the impact of these findings on treatment costs. *See, e.g.*, DX L (Ingber decl. & subpoena); DX M (Cullen decl. & subpoena); DX N (Radcliffe subpoena).[26/] The federal government never alleged any wrongdoing related to Purdue's findings that OxyContin is twice as potent as morphine, and indeed it and the thirteen state governments named in the Complaint declined to intervene in this civil FCA lawsuit. *See* Gov't Notice of Election to Decline Intervention [Dkt. 22] (filed May 8, 2007).

ARGUMENT

I. THE COURT LACKS SUBJECT MATTER JURISDICTION OVER RADCLIFFE'S COMPLAINT BECAUSE IT IS BASED ON PUBLIC INFORMATION FOR WHICH HE IS NOT AN ORIGINAL SOURCE

The Court lacks subject matter jurisdiction over a False Claims Act action when the allegations are:

> based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A). Thus, the Court must dismiss this case if the allegations in the Complaint are (1) based upon information that was "publicly disclosed" for which (2) Radcliffe was not the "original source." *See United States ex rel. Grayson v. Adv. Mgmt. Tech., Inc.*, 221 F.3d 580, 582 (4th Cir. 2000). Both requirements are satisfied here. Thus, Radcliffe's Complaint must be dismissed under Federal Rule of Civil Procedure 12(b)(1).

[26/] Radcliffe himself received a subpoena dated July 28, 2005 to appear before the grand jury. DX N (Radcliffe Subpoena).

In resolving a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), "the district court is to regard the pleadings' allegations as mere evidence on the issue, and may consider evidence outside the pleadings without converting the proceeding to one for summary judgment." *Richmond, Fredericksburg & Potomac R.R. Co. v. United States*, 945 F.2d 765, 768 (4th Cir. 1991). The moving party will prevail "if the material jurisdictional facts are not in dispute and the moving party is entitled to prevail as a matter of law." *Id*. The plaintiff bears the burden of demonstrating that the court had subject matter jurisdiction. *See, e.g., Jones v. Am. Postal Workers Union Nat'l*, 192 F.3d 417, 422 (4th Cir. 1999). Radcliffe fails to meet this burden.

A. Radcliffe Based His Allegations upon Public Disclosures.

Radcliffe's Complaint makes plain on its face that it is based on public disclosures, which cannot form the basis of a *qui tam* claim unless the relator is also an original source of the information, as discussed below.

A prior disclosure is "public"[27/] where the disclosure is from "a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media." 31 U.S.C. § 3730(e)(4)(A). Federal courts consistently define these sources expansively.[28/] Thus, the Fourth Circuit held that the term "administrative hearing" includes the filing of an administrative complaint, even

[27/] A relator's action is based upon a prior public disclosure of allegations or transactions where the relator derives from that prior disclosure the allegations or transactions upon which his *qui tam* action is based. *Grayson*, 221 F.3d at 582.

[28/] *See, e.g., United States ex rel. Stinson, Lyons, Gerlin & Bustamante v. Prudential Ins. Co.*, 944 F.2d 1149, 1155-57 (3d Cir. 1991) ("hearing" includes any information disclosed in connection with criminal, civil, or administrative litigation, including narrative memoranda obtained during the discovery process but not filed with the court); *United States ex rel. Bly-Magee v. Premo*, 470 F.3d 914, 919 (9th Cir. 2006) ("[T]he California administrative audit is a source of public disclosure.").

where "the document was [only] available upon request" by members of the public but was not otherwise publicized. *See, e.g., Grayson*, 221 F.3d at 582.

Relevant here, the term "news media" includes scholarly and scientific periodicals, medical reference materials, and instructional materials. *See United States ex rel. Alcohol Found. v. Kalmanovitz Charitable Found.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y. 2002), *aff'd*, No. 02-6097, 2002 WL 3181952 (2d Cir. 2002). As explained by the court in *Alcohol Foundation*, "the ordinary meaning of the statutory term 'news media' would encompass the publication of information in scholarly or scientific periodicals." *Id*. That is so because "[n]o different from newspaper reporters, scholarly and scientific authors also disseminate information to the public in a periodic manner." *Id*; *see also Gold v. Morrison-Knudsen*, 68 F.3d 1475, 1476-77 (2d Cir. 1995) (engineering periodical constituted "news media"); *California ex rel. Grayson v. P. Bell Tel. Co.*, 142 Cal. App. 4th 741, 754-55 (Calif. App. 2006) ("trade journals and periodicals" are "news media"). All of these sources qualify as "news media" because they contain current information about a particular scholarly or professional discipline and are published on a periodic basis. *Id*.

For a set of public disclosures to bar a relator's claim, they must "reveal both the misrepresented state of facts and the true state of facts so that the inference of fraud may be drawn." *See, e.g., United States ex rel. Mistick PBT v. Housing Auth.*, 186 F.3d 376, 385 (3d Cir. 1999) (Alito, J.). In other words, "[s]o long as the information alleged is sufficient to put the government on notice of the likelihood of related fraudulent activity, the prior public disclosure requirement is satisfied." *United States ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 389 (6th Cir. 2005), *cert. denied*, 546 U.S. 1094 (2006). Notably, the alleged misstatement and the

alleged true statements need not be contained in the same source so long as both are publicly disclosed. *See, e.g., id*. at 390.

In sum, if the relator derives his allegations from publicly available periodic publications that collectively disclose both the allegedly "misrepresented" set of facts and the allegedly "true" set of facts, then the relator fails the first part of the test in § 3730(e)(4).

It is plain on its face that Radcliffe's Complaint is based on publicly disclosed information. He admits his information came from "professional literature" and Purdue's single-dose clinical study, which was published twice in periodic scholarly journals,[29/] and, as such, is found in "news media," as that term is interpreted by courts. *See Alcohol Found.*, 186 F. Supp. 2d at 463 (scholarly journals are "news media" because, like newspapers, they "disseminate information to the public in a periodic manner").

For example, for Purdue's alleged misstatement – that OxyContin is twice as potent as morphine – Radcliffe cites Purdue's single-dose relative potency study, published as an abstract in 1996 and fully in 1999. Compl. ¶ 12.[30/] Purdue did not just reveal the alleged misstatements

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[29/] *See* Kaiko, *supra* note 17 (DX H1); Curtis, *supra* note 17, at 428 (H2). Indeed, Radcliffe's claim is plainly wrong that no studies that show OxyContin to be twice as potent as morphine were ever published (*see* Compl. ¶ 22). Numerous such studies were published by Purdue and others. *See supra* at 5-10 & note 17. Many sources also explicitly and publicly discussed the debate about the relative potency of OxyContin. For instance, one author in a periodical journal wrote, "[t]here are several reports in the medical literature suggesting that oral [oxycodone] is at least as potent and may be twice as potent as [morphine]." Anderson, *supra* note 17, at 399 (DX G10); *see also* Coluzzi, *supra* note 17, at 457-58 (DX G3) (noting, after recommending a 2:1 ratio, that someone else "supports the use of 1:1 mg conversion ratio for oral oxycodone and oral morphine."); Souter, *supra* note 17, at 274, 277 (DX G6) (reporting a 2:1 conversion ratio from morphine to controlled-release oxycodone, but acknowledging that "there are a number of differing studies" on the proper ratio.")

The Court may consider these publicly available sources and other evidence outside the pleadings for purposes of a 12(b)(1) motion. *See supra* at 13.

[30/] Radcliffe also alleges that these alleged "false" findings were repeated in the OxyContin package insert. Compl. ¶¶ 11-12. First, statements in the package insert about the conversion ratio are duplicative of statements made in publications by Purdue scientists and researchers working under Purdue. *See* Kaiko, *supra* note 17 (DX H1); Curtis, *supra* note 17, at 428 (DX H2); Kaiko & Beczkowska, *supra* note 17 (DX H3); Salzmann, *supra* note 17, at 273 tbl. 1(DX H4); Bruera, *supra* note 17, at 3227 (DX H5); Ginsberg, *supra* note 17 (DX H6); Benzinger, *supra* note 17 at 75 (DX H7); Heiskanen, *supra* note 17, at 37. Second, the OxyContin package insert, with its conversion table, has been available on Purdue's website since at least 2001. *See* Internet Archived Website Search Machine, Purdue's News, http://web.archive.org/web/20010810115630/www.purduepharma.com/news/default.htm. A disclosure on the Internet constitutes a public disclosure as defined by § 3730(e)(4)(A). *See United States ex rel. Doyle v. Diversified Collection Servs., Inc.*, No. 2:04 CV 053, 2006 WL 3834407, at *3 (S.D. Ohio

(Footnote continued on next page)

in this study, however. Purdue also revealed in that same "news media" source the alleged "true" statements. Purdue explained that "consistent with reports" from other scientists, Purdue found that OxyContin was 1.8 to 2.2 times more potent than controlled-release morphine. Curtis, *supra* note 17, at 428 (H2). Purdue also explained that "different ratios have been reported in multiple dose settings." *Id*. In particular, "[r]eviews of cancer pain management indicate equianalgesic dose ratios of oral oxycodone to oral morphine ranging from 1:2, 2:3, and 1:1." *Id*. Given these different findings, the Purdue authors concluded that physicians should assume OxyContin is twice as potent as morphine when converting patients, as that would result in a smaller starting dose, and should adjust the dose upward as necessary. *Id*.

Radcliffe admits in his Complaint that his information that Purdue's findings on OxyContin's potency were wrong came from "professional literature." Compl. ¶ 12. Radcliffe cites a few examples of the professional literature (Compl. ¶¶ 12, 16, 19, 22, 24); indeed, the alleged "true" 1:1 ratio is contained in many scholarly periodic journals.[31/] And, the sources Radcliffe cites as examples of "the professional literature" plainly fall within the definition of the "news media." He cites: (1) *Clinical Practice Guideline: Acute Pain Management Operative or Medical Procedure and Trauma*, U.S. Dept. of Health and Human Servs., App. C1 (Feb. 1992) (Compl. ¶¶ 12, 24; DX F1); (2) the *United States Pharmacopeia - Dispensing Information* ("*USP DI*") (Compl. ¶ 24; DX F3 (1996 edition, at 2238 tbl.2)); (3) Robert G. Twycross, *Opioids, in*

2006) (unreported). Third, the FDA approved the OxyContin package insert, which included the recommended 2:1 conversion ratio (*see* DX A8 (Dec. 12, 1995 approval letter); RX 2 (Dec. 1995 package insert)) after Purdue informed the FDA during the application process that other sources had reported a 1:1 ratio (*see supra* at 8). Such action constitutes an "administrative investigation" as defined by § 3730(e)(4)(A), because it involves disclosure of the scientific debate regarding the relative potency of OxyContin to the FDA official responsible for investigating and approving Purdue's labeling claims. *See United States ex rel. Mathews v. Bank of Farmington*, 166 F.3d 853, 861-62 (7th Cir. 1999).

[31/] *See, e.g.*, Susannah Hall, et al., *The Terminal Cancer Patient: Effects of Age, Gender, and Primary Tumor Site on Opioid Dose*, 4 (2) Pain Medicine, 125, 127 (2003) (DX F5); Karl E. Miller, *Challenges in Pain Management at the End of Life*, 64 (7) Am. Family Physician 1227, 1233 (2001) (DX F6); Nathan I. Cherny, *Opioid Analgesics: Comparative Features and Prescribing Guidelines*, 51 (5) Drugs 713, 716 (1996) (DX F7); Walter B. Forman, *Opioid Analgesic Drugs in the Elderly*, 12 (3) Pain Management 493 (1996) (DX F8).

Textbook of Pain 943, 953 tbl. 49.7 (Wall and Mezack eds. 3d ed. 1994) (Compl. ¶ 17; DX F2); and (4) pain specialists and oncologists, who in turn based their knowledge on scientific literature (Compl. ¶¶ 16, 17, 19, 24).[32/] Each one of these widely-available scientific publications contained the latest information available at the time of publication on the clinical use of the pain medications. *See Alcohol Found.*, 186 F. Supp. 2d at 463 (considering such sources to be "news media"). Indeed, the *USP DI* and the *Textbook of Pain* are constantly being updated, and new editions are released annually and every couple of years respectively.

Plainly, the extensive publication in the professional literature of both sides of the scientific debate, including articles that reported both that Purdue had found a 2:1 ratio and that other scientists had found a 1:1 ratio, put the government "on notice" of the various studies with different conclusions and thus – to the extent such differences could evidence potential fraud – of the alleged fraud. *Gilligan*, 403 F.3d at 389. Thus, Radcliffe's allegations were based on "publicly disclosed allegations and transactions," which means his Complaint must be dismissed unless he was an "original source" of the information on which his allegations are based.

B. Radcliffe Is Not an "Original Source."

Radcliffe cannot overcome the public disclosure bar of § 3730(e)(4)(A) because he is not an "original source" of his allegations. Radcliffe's Complaint reveals on its face that he does not have direct *and* independent knowledge of the information on which his allegations are based. Because the law requires him to have both to be an "original source," his Complaint must be dismissed.

[32/] Radcliffe alleges: (1) one doctor "turned to the Textbook of Pain Third Edition" and pointed to a table and some text, which asserted that 1:1 was the proper conversion ratio; and (2) another doctor pointed out the 1:1 conversion ratio in a USP publication. Compl. ¶¶ 17, 24. The doctors plainly were passing on what they had read in textbooks, peer-reviewed medical journals, and otherwise public sources.

An original source is "an individual who has direct *and* independent knowledge of the information on which the allegations are based." 31 U.S.C. § 3730(e)(4)(B) (emphasis added); *United States ex rel. Barth v. Ridgedale Elec., Inc.*, 44 F.3d 699, 702-03 (8th Cir. 1995). A relator cannot meet this jurisdictional burden by making a conclusory allegation that his knowledge is independent and direct; rather, the relator is required to allege "specific facts demonstrating [that] his direct and independent knowledge is 'marked by the absence of an intervening agency.'" *United States ex rel. Grynberg v. Praxair, Inc.*, 389 F.3d 1038, 1052 (10th Cir. 2004)

"Independent knowledge" is knowledge that does not depend on public disclosures. *Grayson*, 221 F.3d at 583; *Stinson*, 944 F.2d at 1160. "Direct knowledge" is knowledge obtained without any "intervening agency, instrumentality or influence." *Stinson*, 944 F.2d at 1160 (quoting *Webster's Third New International Dictionary* 640 (1976)). Thus, the relator may not simply report the fruits of someone else's investigation; he may not bring an action when he "did not see the fraud with [his] own eyes or obtain [his] knowledge of it through [his] own labor unmediated by anything else." *Grynberg*, 389 F.3d at 1054; *see also United States ex rel. Devlin v. California*, 84 F.3d 358, 361 (9th Cir. 1996).

Engaging in activities such as putting the public sources together, verifying the information in the public sources, or using specialized knowledge in evaluating the public sources, does not render the relator an original source. *See id.*; *Stinson*, 944 F.2d at 1160. Courts find relators to be original sources where they obtain and report inside information about their employers, not where they adopt the results of someone else's investigations. For example: Relators are not original sources when they use their "specialized experience" to verify or confirm facts they did not originally gather. *Grayson*, 221 F.3d at 583. Similarly, they are not

original sources when they merely rely on secondhand information from subordinates. *See United States ex rel. Fine v. MK-Ferguson Co.*, 99 F.3d 1538, 1547 (10th Cir. 1996).

It is beyond dispute that Radcliffe fails this part of the test: his Complaint makes clear that he did not have direct and independent knowledge. Indeed, his Complaint outlines that precisely the opposite is true, alleging that he derived his information about the allegedly true and allegedly false statements from "professional literature," mostly pointed out to him by outside medical professionals. Compl. ¶¶ 12, 16, 17, 19, 24. For instance, he alleges:

- the belief that oxycodone is equally potent to morphine "had support in the professional literature" (Compl. ¶ 12);
- "Dr. Ozturk turned to the Textbook of Pain . . . directed the Relator to the 1:1 ratio on Table 49.7 and further pointed to paragraphs that explained while single dose studies indicate a 2:1 ratio, since both MS Contin and OxyContin are designed to serve as repeat dosing products, the 1:1 ratio is the correct ratio" (Compl. ¶ 17); and
- "the United States Pharmacopeia (USP) set forth a 1:1 conversion ratio for chronic dosing of morphine, which fact had been brought to Relator's attention by a pain specialist" (Compl. ¶ 24).

His allegations track those in *Devlin*, *Grayson*, and *MK-Ferguson*, where the relators were mere bystanders to the discovery and investigation of the alleged fraud. Because Radcliffe's Complaint is based on public information and he was not an original source with both direct and independent knowledge of that public information, his Complaint is barred by the FCA's jurisdiction-stripping rule. Thus, his Complaint must be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(1).

C. Radcliffe's State Claims Fail for the Same Lack of Jurisdiction.

The state statutes under which Radcliffe also brings his Complaint contain virtually identical jurisdictional limitations to those found in the FCA. *See* Cal. Gov't Code § 12652(d)(3); Del. Code Ann. tit. 6, § 1206(c); Fla. Stat. § 68.087(3); Haw. Rev. Stat. § 661-28; 740 Ill. Comp. Stat. 175/4(e)(4)(A); La. Rev. Stat. Ann. §§ 46:439:1(A)(2), (E); Mass. Gen.

Laws ch. 12, §§ 5A(a); 5G(3); N.H. Rev. Stat. § 167:61-b (V)(c) , -e(III)(d); Tenn. Code Ann. § 71-5-183(e)(2)(A), (B); Va. Code Ann. § 8.01-216.8; D.C. Code § 2-308.15(c)(2)(A); Nev. Rev. Stat. § 357.100(1), (2); Tex. Hum. Res. Code Ann. § 36.113(b). This Court should accordingly construe and analyze the state statutes' jurisdictional limitations consistent with the federal jurisdictional limitations and dismiss the state causes of action as well.

In addition, all of the state statutes require that the relator "voluntarily provide the information to the State before filing an action or Complaint." *Id*. Radcliffe has not alleged that he provided the information to the thirteen named state governments prior to filing his Complaint. For this additional reason, his state claims must all be dismissed.

II. RADCLIFFE FAILS TO STATE A CLAIM FOR RELIEF BECAUSE LEGITIMATE SCIENTIFIC DISPUTES CANNOT GIVE RISE TO FCA LIABILITY

As a matter of law, an FCA action, whether state or federal, cannot be maintained on the basis that a scientific finding or theory is in dispute. Accordingly, Radcliffe's allegations fail to state a claim for which relief may be granted, and therefore must be dismissed under Rule 12(b)(6) of the Federal Rules of Civil Procedure, because he has done nothing more than identify a scientific dispute (that was already well known, for that matter) regarding the relative potency of oxycodone vis-a-vis morphine.

It is well established that legitimate scientific disputes, scientific errors, and debatable scientific judgments cannot form the basis for FCA liability. "Disagreements over scientific methodology," at best reveal a "legitimate scientific dispute," not "fraud." *United States ex rel. Milam v. Regents of Univ. of Cal.*, 912 F. Supp. 868, 886 (D. Md. 1995) (citation omitted). For that reason, district courts do not allow relators to proceed where the relator "presents insufficient evidence to demonstrate that her dispute with [the defendant's conduct] is anything other than a matter of scientific judgment." *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d

1034, 1047-48 (N.D. Ill. 1998), *aff'd*, 183 F.3d 730, 733 (7th Cir. 1999) (Easterbrook, J.) (stating that the court has rejected the notion that "taking one side of a medical or scientific dispute is 'fraud'"). "Mere deviation from scientific norms is insufficient to support a FCA action." *Id.* Rather, "to demonstrate that the claims are 'known to be false' the [relator] must demonstrate that there were 'lies' – and not merely a scientific or technical dispute." *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1033 (D. Nev. 2006).

As the Ninth Circuit explained:

> Without more, the common failings of engineers and other scientists are not culpable under the Act.
>
> . . .
>
> The weakest account of the Act's "requisite intent" is the "knowing presentation of what is known to be false." *Hagood*, 929 F.2d at 1421. The phrase "known to be false" in that sentence does not mean "scientifically untrue"; it means "a lie." The Act is concerned with ferreting out "wrongdoing," not scientific errors. What is false as a matter of science is not, by that very fact, wrong as a matter of morals. The Act would not put either Ptolemy or Copernicus on trial.

United States ex rel. Wang v. FMC Corp., 975 F.2d 1412, 1421 (9th Cir. 1992) (citation omitted).

The concept that the FCA cannot be used to take sides in scientific disputes has been applied in at least two cases within the Fourth Circuit very similar to the instant case. In *Milam*, 912 F. Supp. at 868, the defendants applied for and received federal NIH grants to fund a cancer research center. The grant applications contained statements based on findings from the defendants' earlier research. The relator, another researcher, tried and failed to replicate the defendant's research and brought an FCA action claiming that the defendants' findings were incorrect, and were based on methods not commonly accepted within the scientific community. *Id.* at 886. The court ruled for the defendants. Relying on *Wang*, the court said, "At most, the

Court is presented with a legitimate scientific dispute, not a fraud case. Disagreements over scientific methodology do not give rise to False Claims Act liability. Furthermore, the legal process is not suited to resolving scientific disputes or identifying scientific misconduct." *Id.* (citations omitted).

In *United States ex rel. Prevenslik v. Univ. of Wash.*, No. Civ.A. MJG-02-80, 2003 WL 23573424, at *4 (D. Md. June 20, 2003) (unreported), *aff'd*, 89 Fed. Appx. 410 (4th Cir. 2004), the court relied on *Milam* and *Wang* in dismissing a relator's FCA Complaint for failure to state a claim for which relief may be granted. The individual defendants were scientists who studied a particular physics problem and had repeated some of their findings in applications for NIH grants. The relator was a competing scientist who alleged, based on his own knowledge of the subject, that the defendants' findings were incorrect. Both sides provided the court with citations to publicly available print sources on the subject. Citing *Wang* and *Milam*, the court granted the defendants' motion to dismiss, finding, *inter alia*, that "Relator has failed to state a claim under the FCA because a difference in the interpretation of research results and data with regard to a scientific phenomenon subject to a great debate within the scientific community is not an appropriate basis for a FCA claim." *Id.* at *4.

Radcliffe's allegations in this case are very much like the relator's in *Prevenslik*, except, of course, that Radcliffe is not a scientist and did not personally conduct any contrasting research. As detailed in the Statement of Facts, there has been a longstanding, public discussion in the scientific literature about the relative potency of oxycodone and morphine. *See supra* at pages 6-11. Indeed, Purdue itself reported in a peer-reviewed published article that this debate was on-going. *See* Curtis, *supra* note 17.

In considering this motion to dismiss under Rule 12(b)(6), the Court may take judicial notice of the fact that a scientific debate exists on the relative potency of oxycodone and morphine.[33/] Indeed, the court in *Prevenslik* did just that, noticing a "great debate within the scientific community" reflected in "the scientific and general media." 2003 WL 23573424, at *4 (taking judicial notice by implication). Here too, the Court can notice the numerous articles, discussed *supra* at 6-10, that support the finding that oxycodone is twice as potent as morphine,[34/] those that assert a different finding – that oxycodone is equally potent to morphine,[35/] and those that discuss both sets of findings and the existence of a scientific debate.[36/] These numerous sources demonstrate that the relative potency of oxycodone is at the very least "a scientific phenomenon subject to a great debate within the scientific community," 2003 WL 23573424, at *4. Because, at bottom, Radcliffe's Complaint alleges nothing more than that Purdue's findings are contested by others, his allegations do not state a claim for FCA state or federal liability. *See, e.g.*, *Luckey*, 183 F.3d at 733 (rejecting the notion that "taking one side of a medical or scientific dispute is 'fraud'").

III. RADCLIFFE LACKS STANDING TO BRING CLAIMS AGAINST PURDUE

A party lacks standing to sue when it has released its claims against the defendant. *See Young v. F.D.I.C.*, 103 F.3d 1180, 1194 (4th Cir. 1997). Accordingly, Radcliffe's Complaint must be dismissed because he relinquished his standing to bring claims against Purdue, including

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[33/] *See* Defendants' Request for Judicial Notice, filed concurrently with this Motion to Dismiss.

[34/] *See supra* at 6-11 & note 17.

[35/] *See supra* at 6-11 & notes 13, 33.

[36/] *See supra* at note 29.

as a *qui tam* relator, when he released all claims against Purdue at the termination of his employment.[37/]

"Article III standing . . . enforces the Constitution's case-or-controversy requirement." *Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 11 (2004) (citations omitted). For a plaintiff to have constitutional standing to bring a case, that "plaintiff must allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *Allen v. Wright*, 468 U.S. 737, 751 (1984). This is true even in the unusual structure of a *qui tam* case, in which the relator asserts injury to the government, not to himself personally. *See Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 772-73 (2000). As the Supreme Court has explained, this effects traditional constitutional standing requirements because statutes authorizing *qui tam* actions essentially assign to the relator a portion of the government's FCA claim. *Id.* at 773-74 & n.4.

A relator's assigned right to bring a *qui tam* claim can be waived, just as a claim based on an individual's own injury can be waived. Courts regularly enforce releases signed by relators to bar *qui tam* suits. *See United States ex rel. Gebert v. Transport Admin. Servs.*, 260 F.3d 909, 913, 915 (8th Cir. 2001) (upholding dismissal based on release signed to settle bankruptcy-related litigation); *United States ex rel. Hall v. Teledyne Wah Chang Albany*, 104 F.3d 230 (9th Cir. 1997) (upholding dismissal based on release signed in settlement of state-law claims); *United States ex rel. Whitten v. Triad Hosps., Inc.*, No. 2:02-cv-00189, 2005 WL 3741538, at *5 (S.D. Ga. Oct. 27, 2005) (unreported) (court lacked jurisdiction based on release included in

[37/] Because standing is jurisdictional, Purdue's standing argument falls under Rule 12(b)(1), rather than Rule 12(b)(6), and the Court may consider evidence outside the pleadings. *E.g., White Tail Park, Inc. v. Stroube*, 413 F.3d 451, 459 (4th Cir. 2005) ("When a defendant raises standing as the basis for a motion under Rule 12(b)(1) . . . the district court may consider evidence outside the pleadings without converting the proceeding to one for summary judgment.") (internal quotations omitted). As with any other jurisdictional issue, Radcliffe, as the plaintiff, bears the burden of proof. *Id.*

severance agreement), *rev'd on other grounds*, 210 Fed. Appx. 878 (11th Cir. 2006); *Cf. United States ex rel. LaValley v. First Nat'l Bank of Boston*, No. 86-236-MLW, 1994 WL 601874 (D. Mass. Oct. 13, 1994) (unreported) (refusing to permit substitution of parties where the proposed new relator would be an alter ego of a party barred by a prior release).

This Court should do the same. A government's assignment of rights to a *qui tam* relator is effected when the relator knows all he needs to know to bring his action. *See Gebert*, 260 F.3d at 913, 915. Radcliffe's Complaint is based on information he knew no later than 1996. Radcliffe alleges he was trained on the relative potency of OxyContin in or around January 1996 (Compl. ¶ 14), he became aware that Purdue's statements regarding OxyContin's relative potency were allegedly false in March 1996 (Compl. ¶¶ 12, 16-19, 22), and he first brought this alleged falsity to the attention of Purdue supervisors in March 1996 (Compl. ¶ 18). Thus by 1996, Radcliffe knew all he needed to know to bring the suit. He certainly knew it by January 2005, well before he signed his release, because in January 2005 he e-mailed Purdue that he had discussed his potential *qui tam* claim with two private attorneys and two Assistant United States Attorneys. *See supra* at 2-3. Therefore, on August 1, 2005, when Radcliffe signed his release, the government's partial assignment of rights, conferring standing, was already in effect and Radcliffe both knew all he needed to know to bring the present action, and in fact explicitly knew that he had a potential *qui tam* claim.

In addition, Radcliffe's release was complete. In the Release, Radcliffe

> knowingly and voluntarily release[ed] and forever discharg[ed] the Company . . . of and from any and all liability to [Radcliffe] for actions or causes of actions, suits, [or] claims . . . whatsoever, in law or equity, which [Radcliffe] . . . ever had, may now have or hereafter can, shall or may have . . . as of the date of the execution of this Agreement.

See DX A5 at 1-3 (Agreement and General Release Packet ¶ 4(a)). Radcliffe also agreed that he "waive[d] any right to accept any relief or award from any charge or action against The Purdue Associated Entities before any . . . federal . . . court . . . with respect to any claim or right covered by" the Release. *Id*. at 3(Release ¶ 5). Radcliffe further affirmed that through these provisions, he

> INTEND[ED] TO WAIVE, SETTLE AND RELEASE ALL LIABILITY FOR AND RECOVERY FROM CLAIMS [HE] EVER HAD, NOW HAS OR MIGHT HAVE AGAINST THE COMPANY AS OF THE DATE OF THE EXECUTION OF THIS AGREEMENT.

Id. at 7-8 (Release ¶ 16). Radcliffe had more than forty-five days to consider the Release before signing it, was urged to review the Release with an attorney, and was given an additional seven days after he signed the agreement (August 1, 2005) to revoke the agreement. *Id*. at 2A, 6 (Release ¶ 13).

Radcliffe's complete release of claims against Purdue plainly covered the claims at issue in this action because it covered all claims he had as of August 1, 2005, and he was fully aware of his *qui tam* claims by then. In releasing the claims at issue in this lawsuit, Radcliffe relinquished the rights against Purdue assigned to him by the state and federal governments by virtue of the statutes authorizing *qui tam* actions. *See Vermont Agency of Natural Res.*, 529 U.S. at 773-74 & n.4. He thus no longer has standing to bring the present action, and it must be dismissed.[38/]

[38/] This result is fully consistent with public policy. In enacting the *qui tam* provisions of the False Claims Act, Congress sought to encourage private parties to approach the government and disclose fraud. *Gebert*, 260 F.3d at 909, 913-15 (holding enforcement of pre-Complaint release consistent with public policy); *Hall*, 104 F.3d at 232-33 (same). Where those private parties choose to settle with defendants after fully learning of the alleged fraud, discussing it with private attorneys, and approaching the government to disclose the alleged fraud – as happened here – such settlements do not interfere with the public policy interests underlying the FCA. As detailed above, *see supra* at 3-4, Radcliffe signed the Release well after learning everything he needed to know to bring the instant action, and after discussing his claims with two private attorneys and two Assistant United States Attorneys. In addition, at the time Radcliffe signed his release, investigators from the United States Attorney's Office for the Western District of Virginia, the Office of Consumer Litigation of the HHS Office of Inspector General ("OCL"),

(Footnote continued on next page)

IV. RADCLIFFE FAILS TO PLEAD FRAUD WITH THE PARTICULARITY REQUIRED BY RULE 9(B)

At the very minimum, the Court must dismiss Radcliffe's Complaint for failure to plead fraud with particularity. An FCA action, like other causes of action pleading fraud, must be pleaded with specificity. *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783 (4th Cir. 1999). "[T]he 'circumstances' required to be pled with particularity under Rule 9(b) are 'the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.'" *Id*. at 784 (quoting 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure: Civil § 1297, at 590 (2d ed. 1990). In particular, an FCA relator cannot "merely . . . describe a private scheme in detail but then . . . allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002).

This rule exists to ensure "the defendant has sufficient information to formulate a defense by putting it on notice of the conduct complained of." *Harrison*, 176 F.3d at 784. Furthermore, "lack of compliance with Rule 9(b)'s pleading requirements is treated as a failure to state a claim

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and several other state and federal agencies were three years into a major, wide-ranging investigation into, *inter alia*, Purdue's marketing of OxyContin. Indeed, the very day after Radcliffe signed his release, August 2, 2005, the federal government executed a subpoena that called for "[a]ll documents" in Purdue's custody related to "the relative analgesic potency" of OxyContin, (s*ee* DX K (Request 4 of Grand Jury Subpoena 513)), and prior to that the government subpoenaed witnesses to testify about relative potency (*see* DX L (Ingber Decl.); DX M (Cullen Decl.); DX N (Radcliffe subpoena)). Finally, such a result cannot harm public policy in circumstances such as these where the federal and state governments have all determined the relator's claims are so weak that they have declined to intervene. *See Whitten., Inc.*, 2005 WL 3741538, at *5 ("[T]he public policy interest [of] . . . encouraging disclosure of allegations of fraud against the government, is served adequately by a rule that prohibits a litigant who has agreed to release his right to serve as a relator from maintaining a *qui tam* action if the government declines to intervene in the action."). Indeed, the governments' decisions not to intervene indicate that Radcliffe's decision to settle early made perfect sense.

under Rule 12(b)(6)." *Id*. at n. 5. Here, Radcliffe's Third Amended Complaint omits the necessary detail and specifics required under Rule 9(b) and thus it must be dismissed.

First, Radcliffe fails to specify which of the ***seven*** subdivisions of the FCA's liability provision, 31 U.S.C. § 3729(a), Purdue allegedly violated. *See* Compl. ¶ 33. Purdue therefore cannot know, for example, whether his theory is that Purdue actually submitted false claims, § 3729(a)(1), or that it made false statements to get such claims paid, § 3729(a)(2), or that it conspired to defraud the government, § 3729(a)(3).

Second, Radcliffe's allegations of violations of thirteen different state statutes are so lacking in specificity as to be useless for the purpose of planning a defense. Indeed, Radcliffe does not even cite the provisions defining prohibited conduct under the state statutes. Instead, he cites *the entire state statutes* or the entirety of the provisions authorizing *qui tam* suits. *See* Compl. ¶ 40. Purdue cannot adequately mount a defense without notice of the specific provisions of the laws it has allegedly broken, especially when the possibilities vary so widely.

Third, assuming that Radcliffe intends to invoke § 3729(a)(1) – prohibiting the submission or causing of the submission of a "false or fraudulent claim for payment or approval" – he has made a separate fatal omission to provide any details regarding actual "false or fraudulent claim[s]" for government payment that were caused by the alleged false statements regarding OxyContin's relative potency. A "false or fraudulent claim" submitted to the government for payment is the "the *sine qua non* of a False Claims Act violation." *Clausen*, 290 F.3d at 1311; *see also Harrison*, 176 F.3d at 785 ("[T]he False Claims Act at least requires the presence of a claim – a call upon the government fisc – for liability to attach."). It is, therefore, well settled that an FCA Complaint must "provide[s] details that identify particular false claims for payment that were submitted to the government." *United States ex rel. Karvelas v. Melrose-*

Wakefield Hosp., 360 F.3d 220, 232-35 (1st Cir. 2004). Courts will thus dismiss an FCA Complaint that "never specifies the dates or content of any particular false or fraudulent claim allegedly submitted for reimbursement by Medicare or Medicaid," "provides no identification numbers or amounts charged in individual claims," and "does not identify or describe the individuals involved in the improper billing or allege with particularity any certification of compliance with federal regulations in order to obtain payments." *Id*. Similarly, Courts will dismiss a relator's claim where the Complaint fails to identify the "specific claim" submitted by the defendants. *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997).

Radcliffe fails to meet this specificity requirement. He does not provide any description or detail regarding a false or fraudulent claim submitted to the government on the basis of Purdue's alleged "misrepresentations." [39/]

Fourth, in addition to failing to provide details about a single actual false claim, Radcliffe fails to advance even a theory as to how such claims could have occurred. A successful FCA action requires that the defendant engaged in some fraudulent conduct that "caused the government to pay out money or to forfeit moneys due." *Harrison*, 176 F.3d at 788. Where these alleged "claims" are requests for payment or reimbursement submitted by physicians to Medicaid (or any government payor), the "Plaintiff ***must plead*** that ***but for*** Defendant's allegedly fraudulent misrepresentations the doctors would not have made claims to Medicare. . . and that ***but for*** these allegedly fraudulent misrepresentations Medicare would not have

[39/] Radcliffe states in his Complaint that he cannot be more specific because the information on specific false claims is outside of his control. Compl. ¶ 36. However, a *qui tam* relator cannot rely on discovery to help him comply with Rule 9(b); the Complaint must contain specific allegations of false claims in the first instance. *See United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 559 (8th Cir. 2006), *cert. denied*, 127 S. Ct. 189 (2006); *Karvelas*, 360 F.3d at 231; *United States ex rel. Russell v. Epic Healthcare Mgmt. Group*, 193 F.3d 304, 308 (5th Cir. 1999); *Clausen*, 290 F.3d at 1313 n.24.

reimbursed the doctors." *United States ex rel. Hess v. Sanofi-Synthelabo, Inc.*, No. 4:05-CV-570, 2006 WL 1064127, at *7 (E.D. Mo. Apr. 21, 2006) (unreported) (emphasis added). In other words, the relator must allege that the defendant's fraudulent conduct was the single "but for" cause of the prescriptions written by doctors and thus the cause of the government paying out money it would not have otherwise paid.

Radcliffe does not plead that Purdue's statements about the potency of OxyContin were the *only* reason doctors prescribed OxyContin. Indeed, he specifically alleges the opposite. He admits that some doctors prescribe OxyContin for patients "who could not tolerate MS Contin or other less expensive medications." Compl. ¶ 16. And in these instances and any others in which OxyContin was the medication of choice for a reason other than its potency vis-à-vis morphine, Purdue's allegedly false statements about the relative potency of OxyContin would not be a "but for" cause of any false claims. That is, if doctors prescribed OxyContin because it is easier on the stomach, then the statements regarding its relative potency are not the reason the doctors prescribed the medication and correspondingly sought reimbursement from the government. Similarly, if a doctor converted a patient to OxyContin from morphine using a 2:1 ratio, and adjusted the dose upwards until effective pain relief was achieved, as recommended in the OxyContin package insert (*see* RX 2; DX C; DX D), then although the first prescription might be based on the package insert's conversion guidance, none of the subsequent prescriptions would be. Rather, they would be based on the doctors' clinical judgments about their patients.

Fifth, the Third Amended Complaint is internally inconsistent in its definitions of the allegedly "false claims" submitted to the government. In one paragraph, the claims are something that "resulted" from "each prescription written by a physician for OxyContin for a

Medicaid patient" (Compl. ¶ 34); in the next, the claims are "every prescription for OxyContin that was written during the period of Purdue's Phase II marketing that was submitted to Medicaid (or other government programs)" (*Id.* ¶ 35). Thus, it is unclear whether the number of alleged false claims could be equal to the total number of OxyContin prescriptions written for Medicaid patients between 1996 and the date the Complaint was filed or the number of prescriptions for OxyContin "written during the period of Purdue's Phase II marketing [and] submitted to Medicaid (or other government programs)."

The utter lack of specificity as to what provisions of the FCA and state acts were allegedly violated, how Purdue "caused" false claims to be submitted, and in what time-period he alleges "false claims" were submitted, constitutes a failure to comply with the requirements of Rule 9(b). Accordingly, the Complaint must be dismissed.

V. THE STATUTE OF LIMITATIONS BARS RECOVERY ON MANY OF RADCLIFFE'S ALLEGED CLAIMS

The FCA directs that "[a] civil action under section 3730 may not be brought more than 6 years after the date on which the violation of section 3729 is committed." 31 U.S.C. § 3731(b)(1). This statute of limitations begins to run on the date each claim for payment is presented. *See e.g. United States v. Rivera*, 55 F.3d 703, 708 (1st Cir. 1995). And "[t]he raising of the statute of limitations as a bar to plaintiffs' cause of action constitutes an affirmative defense and may be raised by motion pursuant to Fed. R. Civ. P. 12(b)(6), if the time bar is apparent on the face of the Complaint." *See e.g Dean v. Pilgrim's Pride Corp.*, 395 F.3d 471, 474 (4th Cir. 2005).

Radcliffe filed his initial Complaint on September 27, 2005. Thus, any recovery based upon requests for payment presented to the federal government prior to September 27, 1999 may not be considered in this action and must be dismissed.

The FCA statutes of Delaware, District of Columbia, Florida, Illinois, Massachusetts, Nevada, New Hampshire, Tennessee, and Virginia contain virtually identical limitations. *See* Del. Code Ann. tit. 6, § 1209(a); D.C. Code § 2-308.17(a); Fla. Stat. § 68.089; 740 Ill. Comp. Stat. 175/5; Mass. Gen. Laws ch. 12, § 5K; Nev. Rev. Stat. § 357.170(1); N.H. Rev. Stat. § 167:61-b (VII); Tenn. Code Ann. § 71-5-184(e)(b); Va. Code Ann. § 8.01-216.9. This Court should accordingly construe and analyze these state acts consistent with § 3731(b); therefore, the Court should preclude any recovery before September 27, 1999 under these states' acts.

VI. THE COURT SHOULD ALSO DISMISS RADCLIFFE'S STATE CLAIMS FOR VIOLATION OF A NUMBER OF STATE REQUIREMENTS

A. The Court Should Dismiss Radcliffe's Claims under the Texas and New Hampshire Acts Because Those States Declined to Intervene.

The Texas and New Hampshire false claims acts require dismissal if the state government declines intervention. Tex. Hum. Res. Code Ann. § 36.104(b);[40/] N.H. Rev. Stat. § 167:61-c.II.e.2. All thirteen of the states named in the Complaint, including Texas and New Hampshire, declined to intervene. Government's Notice of Election to Decline Intervention at 1[Dkt. 22]. Radcliffe's claims under the Texas and New Hampshire acts, therefore, must be dismissed.

B. The Court Should Dismiss Radcliffe's Claims under the Louisiana Act as Untimely and for Failure to State a Claim.

The Louisiana act requires filing the Complaint within one year from the date the relator "knew or should have known of the information forming the basis of the Complaint." La. Rev. Stat. Ann. § 46:439.2A(2)(b). The filing must include the "Complaint and written disclosure of substantially all material evidence and information" with state authorities. *Id*.

[40/] The Texas legislature recently amended the Texas Act to allow relators to proceed if the state declines intervention, but the amendment is effective only for claims submitted after May 4, 2007. *See* Tex. Sess. Law Serx. Ch. 78 (H.B. 889) (Vernon's).

Radcliffe fails to satisfy this provision because on the face of his Complaint, he makes clear that he knew of the substance of his Complaint more than year before he filed it. As discussed *supra* at 26, Radcliffe knew all the material information he alleges in his Complaint by March 1996. He filed his Complaint in September 27, 2005. Thus, by admission in his own Complaint, Radcliffe filed suit much more than one year after he "knew or should have known of the information forming the basis of the Complaint."

Furthermore, Louisiana's statute defines "false or fraudulent claim" to require that the "health care provider" or "billing agent," who actually submitted the allegedly false request for payment, knew it was false. *See* La. Rev. Stat. Ann. § 46:437.3(8). Radcliffe has made no such allegations in his Complaint. His claims under the Louisiana Act, therefore, must be dismissed.

C. The Louisiana and Massachusetts Acts Require Claims to Be Brought in State Court; the Court Should, Therefore, Dismiss These Claims.

The Louisiana and Massachusetts acts authorize claims in the respective state's own courts. La. Rev. Stat. Ann. § 46:439.1A, 438.1(A) (authorizing *qui tam* suits and suits by the state to be brought in "the courts of this state"); *id*. at § 46:439.2 (requiring that *qui tam* complaints have a specific caption, providing certain time limits within which the Complaint and information "may be filed with the appropriate state district court," and making the relator's failure to comply with any requirement in the subpart ground for dismissal); Mass. Gen. Laws Ann. 12 § 5C(1) & (2) (authorizing civil actions by a *qui tam* relator or the Attorney General in "superior court"). Radcliffe did not first file his actions under the Louisiana and Massachusetts Acts in the respective state courts; therefore, these state claims must be dismissed.

D. Five State Acts Do Not Apply Retroactively.

The Delaware, District of Columbia, Hawaii, New Hampshire, and Virginia false claims act do not apply retroactively; therefore, Radcliffe cannot recover for the allegedly false requests

for payment submitted to these state governments before the dates of enactment. First, the District of Columbia and New Hampshire acts expressly state that a relator may not recover prior to enactment. D.C. Code § 2-308.17(b) (A civil action brought pursuant to § 2-308.15 may not be brought for activity prior to April 12, 1997); N.H. Rev. Stat. § 167:61-e ("No provision of this act shall apply with respect to any claim . . . . submitted prior to January 1, 2005."). Second, when a statute does not address retroactivity, courts follow a presumption against statutory retroactivity. *See Landgraf v. USI Film Prods.*, 511 U.S. 244, 245 (1994). Thus, Radcliffe cannot recover for any requests for payment from the Delaware, Hawaii, and Virginia governments prior to the enactment of those statutes. Del. Code Ann. tit. 6, § 1201 (effective June 30, 2000); Haw. Rev. Stat. § 661-21(effective May 26, 2000); Va. Code Ann. § 8.01-216.1 (effective January 1, 2003).

In sum, the Court should dismiss all claims under the District of Columbia act prior to April 12, 1997, the New Hampshire act prior to January 1, 2005, the Delaware act prior to June 30, 2000, the Hawaii act prior to May 26, 2000, and the Virginia act prior to January 1, 2003.

CONCLUSION

Pursuant to Rules 12(b)(1), 12(b)(6), and 9(b) of the Federal Rules of Civil Procedure, Purdue respectfully moves the Court to dismiss Radcliffe's Complaint with prejudice and grant Purdue such other relief as the Court deems just and equitable.

Respectfully Submitted,

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